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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
07/330,156	03/29/89	MOHIUDDIN	S 167109CIP

EXAMINER: POLUTTA, M

ART UNIT	PAPER NUMBER
336	18

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DATE MAILED: 06/03/91

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☑ This application has been examined ☑ Responsive to communication filed on 2/28/91 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), ⟶ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☑ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice re Patent Drawing, PTO-948.
3. ☑ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, Form PTO-152
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____.

Part II SUMMARY OF ACTION

1. ☑ Claims 1 - 68 are pending in the application.

   Of the above, claims _____ are withdrawn from consideration.

2. ☑ Claims 1-21 have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☑ Claims 22-68 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____ ; filed on _____.
13. ☐ Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

PTO-326 (Rev. 9-95) EXAMINER'S ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (f) he did not himself invent the subject matter sought to be patented.

Claims 22-25, 28-31, 34, 36, 37, 58-60, and 63-68 are rejected under 35 U.S.C. § 102(e) as being anticipated by Zijlstra et al...

Zijlstra et al. disclose a method of assessing coronary flow reserve using adenosine in bolus injections ranging from 0.05mg-0.8mg.

Claims 26, 27, 32, 33, 35, 38-57, 61 and 62 are rejected under 35 U.S.C. § 103 as being unpatentable over Zijlstra et al..

Zijlstra et al. disclose a method for assessing myocardial disfunction comprising the use of adenosine and a doppler catheter.

While Zijlstra does not disclose the use of intravenous infusion, and the other types of imaging, they are all

conventional methods known in the art.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to image the heart and coronary arteries using adenosine and any of the known imaging techniques.

Claims 22-68 are rejected under 35 U.S.C. § 103 as being unpatentable over Strauss et al..

Strauss et al. teach myocardial perfusion imaging after the administration of ethyl adenosine-5-carboxylate-and thallium-201.

Adenosine is used to induce differential perfusion between normal coronary beds and those distal to a substantial stenosis, and myocardial perfusion imaging is used to detect the resultant difference in regional perfusion.

With regard to the different types of myocardial perfusion imaging and blood flow velocity measuring, these are well known and conventionally used methods in the art.

With respect to the different dosages, the optimal dosage would be found through routine experimentation.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use adenosine as a vasodilator in humans to replace patient exercise stress testing because Strauss et al. suggested its use in humans.

Claims 22-68 are rejected under 35 U.S.C. § 103 as being unpatentable over Rubberger et al..

Rumberger et al. disclose the use of computed tomography to image myocardial perfusion employing adenosine as a vasodilator

Rumberger discloses that either bolus injection or intravenous infusion may be used to administer adenosine.

With respect to the dosages, the optimal dosages would be found through routine experimentation.

With regard to the different types of analysis, they are all well known conventional methods used in the art.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use adenosine as a vasodilator in assessing for myocardial dysfunction in humans because Rumberger suggest it and animal testing is used to check for safety before use in humans.

Claims 22-68 are rejected under 35 U.S.C. § 103 as being unpatentable over Watt et al..

Watt et al. disclose the use of adenosine as a vasodilator in analyzing blood flow in human patients suffering from chest pain.

Watt discloses the use of a Baim thermodilution catheter to measure blood flow.

He also disclosed that the patients treated with the higher dose of adenosine suffered from chest pain and that no other symptoms were reported.

It would have been obvious to one of ordinary skill in the

art at the time the invention was made to use adenosine as a vasodilator in assessing myocardial dysfunction because Watt suggest that it could be used to replace atrial pacing to assess physiological or pharmacological interventions.

With regard to the different types of imaging, they are all well known and conventional in the art.

With regard to the specific dosages, the optimal dosages would be found through routine experimentations.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Biaggioni et al. disclose that adenosine may be administered in bolus injections or by intravenous infusion (10 to 140 ng/kg/min) in conscious subjects to act as a vasodilator.

Berne et al. '563 disclose that adenosine may be safely administered in the treatment of supraventricular tachycardia. Berne also discloses that adenosine-induced transient A-V block, atrial flutter or fibrillation can be unmasked on the body surface EKG recording in order to more clearly diagnose the disorder (4:40-45).

Any inquiry concerning this communication should be directed to Mark Polutta at telephone number (703) 308-0858.

mp
M.Polutta/dr
May 21, 1991
May 24, 1991

C. FRED ROSENBAUM
S. P. E.
ART UNIT 336